DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

- 2871. Adulteration and misbranding of Neo-Mineral. U. S. v. 13 Cases * * *. (and 1 other seizure action). (F. D. C. Nos. 27344, 27347. Sample Nos. 47125-K, 51550-K.)
- LIBELS FILED: June 21 and 24, 1949, Northern District of Ohio.
- ALLEGED SHIPMENT: On or about February 25 and May 21, 1949, by Neo-Mineral Co., Inc., from Detroit, Mich.
- PRODUCT: Neo-Mineral. 96 3-ounce bottles at Bowling Green, Ohio, and 13 cases, each containing 36 3-ounce bottles, at Youngstown, Ohio. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.
- LABEL, IN PART: (Bottle) "Neo-Mineral. * * * Take one teaspoonful twice daily, in a full glass of water."
- NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.
 - Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. Newspaper mats entitled "Sick" and "Health News" had been supplied by the shipper and were used for advertisements appearing in the Youngstown and Bowling Green newspapers.
- DISPOSITION: August 1 and 5, 1949. Default decrees of condemnation and destruction.
- 2872. Misbranding of Vitalic vitamin and mineral tablets and Vitalic calcium and phosphorus tablets with vitamin D. U.S. v. 20 Bottles, etc. (F. D. C. No. 27587. Sample Nos. 55239-K, 55240-K.)
- LIBEL FILED: On or about July 28, 1949, Western District of Missouri.
- ALLEGED SHIPMENT: On or about June 25, 1949, by Thomas Gaines, from Los Angeles, Calif.
- PRODUCT: 20 bottles of Vitalic vitamin and mineral tablets and 9 bottles of Vitalic calcium and phosphorus tablets with vitamin D at Kansas City, Mo.
- LABEL, IN PART: "Vitalic * * * Vitamins and Minerals Vitamins: A, C, D, E, and B-Complex Minerals: Calcium, Iron, Phosphorus 60 Tablets [or "Vitalic Calcium Phosphorus Tablets With Vitamin D Each tablet contains: Dicalcium Phosphate 12½ grs. Vitamin D . . . 250 U. S. P. Units (Irradiated Ergosterol) Contents: 100 Tablets"] * * * Manufactured For and Distributed by Thomas Gaines 458 North Edinburgh Ave., Los Angeles 36, California."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended. The Vitalic vitamin and mineral tablets were offered for use in the treatment of cancer, high blood pressure, diabetes, and heart trouble, and to cure and prevent colds, to prevent contagious diseases of childhood, to thin the blood, to keep one young, to rid the body of lice, to stop tooth decay, and to prevent tiredness; the Vitalic calcium and phosphorus tablets with vitamin D were offered for use in the treatment of stomach troubles and to prevent tooth decay. The articles were offered for use in such conditions at lectures delivered in Kansas City, Mo., by Thomas Gaines, on or about June 25, 27, 28, and 29, 1949. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1949. Default decree of destruction.

2873. Misbranding of Sun-O-Ray Ointment. U. S. v. 656 Jars, etc. (F. D. C. No. 27306. Sample No. 51921–K.)

LIBEL FILED: June 8, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: The product was shipped on or about May 11 and 13, 1949, by the Crestline Co., from Chicago, Ill., and a number of circulars were transported by George R. Thurman, from the Crestline Co., on or about May 4, 1949.

PRODUCT: 210 14-ounce jars and 446 4-ounce jars of Sun-O-Ray Ointment at Cincinnati, Ohio, in the possession of George R. Thurman, together with a number of circulars entitled "Sun-O-Ray Compound."

The product was offered by Mr. Thurman, during lectures delivered by him at Cincinnati, Ohio, on May 12, 1949, for varicose veins, swollen ankles, stiff knees, and pains of arthritis and swollen joints, conditions for which the product failed to bear any directions for use. Examination showed that the product consisted of a mixture of volatile oils, including safrol, camphor, menthol, and eucalyptol, in a greaseless ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circulars were false and misleading since the article was not effective in the treatment of bunions: "Bunions * * * have been eased through brisk massage with Sun-O-Ray Foot Ointment by increasing blood circulation." The article was misbranded in this respect when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

Disposition: September 2, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2874. Adulteration of water for injection. U.S.v. 36 Bottles * * *. (F.D.C. No. 27473. Sample No. 27734-K.)

LIBEL FILED: July 18, 1949, Southern District of Illinois.

ALLEGED SHIPMENT: On or about June 28, 1948, from Detroit, Mich.